REMARKS

Claims 1-53 were pending in the present application. Claims 46-52 were canceled in this Preliminary Amendment. Claims 1-28, 30-38, 41-43 and 45 were amended in order to format the claims for prosecution in the U.S. Patent and Trademark Office, and to correct occasional typographical errors. These amendments address formalities and do not affect patentability of the subject matter of any claim or alter the scope of the claims in any way.

New claims 54-103 were added in order to more fully define the subject matter Applicants regard as their invention. No new matter has been added.

Respectfully Submitted,

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Marked-up Version Showing Changes Made:

(unchanged claims shown in small type)

1. (Amended) A method of making [Use of hCG for the manufacture of] a medicament for treatment of mammary tumors, comprising incorporating hCG into the medicament in an amount effective to treat the mammary tumors.

2. (Amended) The method of claim 1, wherein the medicament is [Use of hCG according to claim 1, for the manufacture of a medicament] for the treatment of clinically manifest mammary tumors.

3. (Amended) The method of [Use according to] claim 2, wherein the clinically manifest mammary tumor is a primary tumor.

4. (Amended) The method of claim 1, [Use according to any of the preceding claims,] wherein the tumor is a non-invasive carcinoma.

5. (Amended) The method of [Use according to] claim 4, wherein the tumor is ductal carcinoma *in situ* or lobular carcinoma *in situ*.

6. (Amended) The method of claim 1, [Use according to any of claims 1 to 3,] wherein the tumor is an invasive carcinoma.

7. (Amended) The method of [Use according to] claim 6, wherein the tumor is tubular or lobular invasive carcinoma.

8. (Amended) The method of [Use according to] claim 2, wherein the clinically manifest mammary tumor is a metastatic mammary tumor.

9. (Amended) The method of claim 1, wherein the medicament is [Use of hCG for the manufacture of a medicament] for the treatment **[and/]**or prevention of mammary tumors in premenopausal or postmenopausal women.

10. (Amended) The method of claim 1, wherein the medicament [Use according to any of the preceding claims, wherein hCG] is used [as an adjuvant] in combination with at least one other cancer therapy.

11. (Amended) The method of [Use according to] claim 10, wherein the other cancer therapy is surgery or chemotherapy.

12. (Amended) The method of claim 1 [Use according to any of the preceding claims], wherein the mammary tumors comprise [treated tumor] cells that are estrogen receptor-positive.

13. (Amended) The method of [Use according to] claim 12, wherein the medicament [hCG] is used in combination with an antiestrogen.

14. (Amended) The method of claim [Use according to] claim 13 , wherein the medicament [in which hCG] is used simultaneously, sequentially or separately with the antiestrogen.

15. (Amended) The method of claim 13 [Use according to claims 13 or 14], wherein the antiestrogen is Tamoxifen.

16. (Amended) The method of [Use according to] claim 15, wherein Tamoxifen is administered orally in a daily amount of about 30 milligrams.

17. (Amended) The method of claim 1, wherein the medicament comprises an amount of hCG that enables administration [Use according to any of the preceding claims, wherein hCG is administered in an amount] of 100 to 20,000 IU of hCG to a [per] patient per day.

18. (Amended) The method of claim 1, wherein the medicament comprises an amount of hCG that enables administration [Use according to any of the preceding claims, wherein hCG is administered in amount] of 50 to 50,000 micrograms of hCG to a [per] patient per day.

19. (Amended) The method of [Use according to] claim 18, wherein hCG is administered in an amount of 250 to 3,000 micrograms [per patient] per day.

20. (Amended) The method of claim 1, wherein the medicament is formulated to enable administration thereof [Use according to any of the preceding claims, wherein hCG is administered] every second day.

21. (Amended) The method of claim 1, wherein the medicament is formulated to enable administration thereof [Use according to any of the preceding claims, wherein hCG is administered] three times a week.

22. (Amended) The method of claim 1, wherein the medicament is formulated to enable administration thereof [Use according to any of the preceding claims, wherein hCG is administered] for several weeks.

23. (Amended) The method of [Use according to] claim 22, wherein the medicament

[hCG] is administered for at least 12 weeks.

24. (Amended) The method of claim 1, wherein the medicament is formulated for subcutaneous administration [Use according to any of the preceding claims, wherein hCG is administered subcutaneously].

25. (Amended) The method of claim 13, wherein the medicament is used in combination with [Use according to any of the preceding claims, further comprising the use of] Type 1 interferon and the [in combination with hCG and] antiestrogen.

26. (Amended) The method of claim 1, [Use according to any of the preceding claims], wherein the hCG is recombinant hCG.

27. (Amended) The method of claim 1 [Use according to any of claims 1 to 25], wherein the hCG is replaced by a protein having the biological activity of hCG [and/]or a binding activity toward a [the] hCG receptor.

28. (Amended) The method of [Use according to] claim 27, wherein the protein is selected from the group consisting of LH, recombinant LH, LH fusion molecule, TSH fusion molecules and FSH fusion molecules.

29. (Not changed) A pharmaceutical composition comprising a pharmaceutically active amount of hCG, in the presence of one or more pharmaceutically acceptable excipients, for the treatment of breast cancer.

30. (Amended) The pharmaceutical composition of claim 29, formulated for administration of the hCG [wherein hCG is administered] in an amount of 100 to 20,000 IU to a [per] patient per day.

31. (Amended) The pharmaceutical composition of claim 29 [or 30], formulated for administration of the hCG [wherein hCG is administered] in an amount of 50 to 50,000 micrograms to a [per] patient per day.

32. (Amended) The pharmaceutical composition of claim 31 [any of claims 29-31], wherein the hCG is administered in an amount of 250 to 3,000 micrograms [per patient] per day.

33. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 32], formulated for administration [wherein hCG is administered] every second day.

34. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 32], formulated for administration [wherein hCG is administered] three times a week.

35. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 34], formulated for administration [wherein hCG is administered] for several weeks.

36. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 35], formulated for administration [wherein hCG is administered] for at least 12 weeks.

37. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 36], formulated for subcutaneous administration [wherein hCG is administered subcutaneously].

38. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 37], which is used simultaneously, sequentially or separately with an antiestrogen.

39. (No change) The pharmaceutical composition of claim 38, wherein the antiestrogen is Tamoxifen.

40. (No change) The pharmaceutical composition of claim 39, wherein Tamoxifen is administered orally in a daily amount of about 30 milligrams.

41. (Amended) The pharmaceutical composition of claim 38 [any of claims 38 to 40], which is used in combination with a Type 1 interferon.

42. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 41], wherein hCG is recombinant hCG.

43. (Amended) The pharmaceutical composition of claim 29 [any of claims 29 to 41], wherein hCG is replace by a protein having the biological activity of hCG and/or a binding activity toward the hCG receptor.

44. (No change) The pharmaceutical composition of claim 43, wherein the protein is selected from the group consisting of LH, recombinant LH, LH fusion molecules, FSH fusion molecules and TSH fusion molecules.

45. (Amended) A method of treating or preventing mammary tumors [inhibiting the proliferation of breast cancer cells, comprising administering a host in need thereof an [effective inhibiting] amount of hCG effective to inhibit proliferation of mammary tumor cells.

Cancel claims 46-52.

53. (Amended) An article of manufacture comprising a container, in which is contained a pharmaceutical composition according to claim 29 [any of claims 29 to 44], and which comprises a label stating the use of the pharmaceutical composition for the treatment of breast cancer.

Add the following new claims:

54. (New) The method of claim 45, wherein the mammary tumor is a clinically manifest mammary tumor.

55. (New) The method of claim 54, wherein the clinically manifest mammary tumor is a primary tumor.

56. (New) The method of claim 45, wherein the mammary tumor is a non-invasive carcinoma.

57. (New) The method of claim 56, wherein the carcinoma is ductal carcinoma *in situ* or lobular carcinoma *in situ*.

58. (New) The method of claim 45, wherein the mammary tumor is an invasive carcinoma.

59. (New) The method of claim 58, wherein the carcinoma is tubular or lobular invasive carcinoma.

60. (New) The method of claim 54, wherein the clinically manifest mammary tumor is a metastatic mammary tumor.

61. (New) The method of claim 45, wherein the host is a premenopausal woman.

62. (New) The method of claim 45, wherein the host is a postmenopausal woman.

63. (New) The method of claim 45, combined with at least one other cancer therapy.

64. (New) The method of claim 63, wherein the at least one other cancer therapy is surgery or chemotherapy.

65. (New) The method of claim 45, wherein the mammary tumors comprise cells that are estrogen receptor-positive.

66. (New) The method of claim 64, wherein the hCG is administered in combination with an antiestrogen.

67. (New) The method of claim 66, wherein the hCG is administered simultaneously, sequentially or separately with the antiestrogen.

68. (New) The method of claim 66, wherein the antiestrogen is Tamoxifen.

69. (New) The method of claim 68, wherein the Tamoxifen is administered orally in a daily amount of about 30 milligrams.

70. (New) The method of claim 45, wherein the hCG is administered in an amount of 100 to 20,000 IU per day.

71. (New) The method of claim 45, wherein the hCG is administered in amount of 50 to 50,000 micrograms per day.

72. (New) The method of claim 71, wherein the hCG is administered in an amount of 250 to 3,000 micrograms per day.

73. (New) The method of claim 45, wherein the hCG is administered every second day.

74. (New) The method of claim 45, wherein the hCG is administered three times each week.

75. (New) The method of claim 45, wherein the hCG is administered for several weeks.

76. (New) The method of claim 75, wherein the hCG is administered for at least 12 weeks.

77. (New) The method of claim 45, wherein the hCG is administered subcutaneously.

78. (New) The method of claim 45, wherein the hCG is administered in combination with Type 1 interferon.

79. The method of claim 78, wherein the hCG and Type 1 interferon are administered in combination with an antiestrogen.

80. (New) The method of claim 45, wherein the hCG is recombinant hCG.

81. (New) The method of claim 45, wherein the hCG is replaced by a protein having the biological activity of hCG or a binding activity toward a hCG receptor.

82. (New) The method of claim 81, wherein the protein is selected from the group consisting of LH, recombinant LH, LH fusion molecule, TSH fusion molecules and FSH fusion molecules.

83. (New) A pharmaceutical composition for the treatment of breast cancer comprising a pharmaceutically active amount of hCG and a pharmaceutically active amount of an antiestrogen,

in the presence of one or more pharmaceutically acceptable excipients.

84. (New) The pharmaceutical composition of claim 83, formulated for administration of the hCG to a patient in an amount of 100 to 20,000 IU per day.

85. (New) The pharmaceutical composition of claim 83, formulated for administration of the hCG to a patient in an amount of 50 to 50,000 micrograms per day.

86. (New) The pharmaceutical composition of 85, wherein the hCG is administered to the patient in an amount of 250 to 3,000 micrograms per day.

87. (New) The pharmaceutical composition of claim 83, wherein the hCG is recombinant hCG.

88. (New) The pharmaceutical composition of claim 83, wherein the antiestrogen is Tamoxifen.

89. (New) The pharmaceutical composition of claim 83, formulated for use in combination with a Type 1 interferon.

90. (New) The pharmaceutical composition of claim 83, formulated for subcutaneous administration.

91. (New) An article of manufacture comprising a container, in which is contained:

a) the pharmaceutical composition of claim 29; and

b) an antiestrogen;

and which comprises a label stating the use of the pharmaceutical composition and the

antiestrogen, together or separately, for the treatment of breast cancer.

92. (New) The article of manufacture of claim 91, wherein the antiestrogen is Tamoxifen.

93. (New) The article of manufacture of claim 92, wherein the Tamoxifen formulated for oral administration in a daily amount of about 30 milligrams.

94. The article of manufacture of claim 91, which further comprises a Type 1 interferon, wherein the label further states the use of the pharmaceutical composition, the antiestrogen and the Type 1 interferon, together or separately, for the treatment of breast cancer.

95. (New) A method of treating or preventing mammary tumors, wherein the tumors comprise cells that are estrogen receptor-positive, the method comprising administering a host in need thereof an amount of hCG effective to inhibit proliferation of mammary tumor cells, wherein the hCG is administered in combination with an antiestrogen.

96. (New) The method of claim 95, wherein the hCG is administered simultaneously, sequentially or separately with the antiestrogen.

97. (New) The method of claim 95, wherein the antiestrogen is Tamoxifen.

98. (New) The method of claim 97, wherein the Tamoxifen is administered orally in a daily amount of about 30 milligrams.

99. (New) The method of claim 95, wherein the hCG is administered in amount of 50 to 50,000 micrograms per day.

100. (New) The method of claim 95, wherein the hCG is administered every second day or three times each week.

101. (New) The method of claim 95, wherein the hCG is administered for several weeks.

102. (New) The method of claim 95, wherein the hCG is administered subcutaneously.

103. (New) The method of claim 95, wherein the hCG and antiestrogen are administered in combination with Type 1 interferon.